UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ALABAMA

LESLIE MORRIS, Individually and as Parent and Natural Guardian of Z.M., a Minor,	)	**CIVIL ACTION NO.: _____**
Plaintiffs,	)	**COMPLAINT**
v.	)	
GLAXOSMITHKLINE, LLC,	)	**JURY DEMANDED**
Defendant.	)	

COMPLAINT AND JURY DEMAND

COME NOW Plaintiffs, Leslie Morris, individually and on behalf of Z.M., a minor ("Plaintiffs"), who by and through undersigned counsel hereby submit this Complaint and Jury Demand against GlaxoSmithKline, LLC d/b/a GlaxoSmithKline ("GSK") for compensatory and punitive damages, treble damages as provided under the Alabama Deceptive Trade Practices Act, equitable relief, and such other relief deemed just and proper arising from the injuries to Plaintiffs as a result of Z.M.'s *in utero* exposure to the generic bioequivalent form of the prescription drug Zofran®, also known as Ondansetron (hereinafter collectively "Zofran"). In support of this Complaint, Plaintiffs allege the following:

PARTIES

1. Plaintiff Leslie Morris is a competent adult and the natural parent of Z.M. She is a resident and citizen of Calhoun County, Alabama. She brings this action individually and on behalf of her minor child to recover for their injuries caused by Z.M.'s exposure to Zofran *in utero*.

2. Z.M. was born in the State of Alabama in 2007 with congenital birth defects, including cleft palate, which required corrective surgery.

3. Upon information and belief, GSK is a limited liability company organized under the laws of the State of Delaware. GSK's sole member is GlaxoSmithKline Holdings, Inc., which is a Delaware corporation, and which has identified its principal place of business as Wilmington, Delaware.

4. GSK is the successor in interest to Glaxo, Inc., and Glaxo Wellcome, Inc. Glaxo, Inc., was the sponsor of the original New Drug Application (NDA) for Zofran. Glaxo, Inc., through its division Cerenex Pharmaceuticals, authored the original package insert and labeling for Zofran, including warnings and precautions attendant to its use. Glaxo Wellcome Inc., sponsored additional NDAs for Zofran, monitored and evaluated post-market adverse event reports arising from Zofran, and authored product labeling for Zofran. The term "GSK" used herein refers to GSK, its predecessors Glaxo, Inc., and Glaxo Wellcome Inc., and other GSK predecessors and/or affiliates that discovery reveals were involved in the testing, development, manufacture, marketing, sale and/or distribution of Zofran.

5. At all times relevant, GSK designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed Zofran.

6. At all relevant times, GSK conducted business in Alabama and derived substantial revenue from products, including Zofran, sold in Alabama.

JURISDICTION AND VENUE

7. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332 as the amount in controversy exceeds $75,000.00, exclusive of interest and costs, and GSK is incorporated and has its principal place of business in a state other than Alabama.

8. Venue in this judicial district is proper under 28 U.S.C. § 1391 inasmuch as a substantial part of the events or omissions giving rise to the claim occurred in Alabama.

9. At all times herein mentioned, GSK engaged in interstate commerce in this judicial district in that it advertised, promoted, marketed, supplied, and/or sold pharmaceutical products, including Zofran, to distributors and retailers for resale to physicians, hospitals, medical practitioners, and the general public in this district, deriving substantial revenue in this district.

NATURE OF ACTION

10. This is a personal injury products liability case arising out of injuries to Z.M., who was born with congenital birth defects, including a cleft palate, as a result of her *in utero* exposure to Zofran, and derivative injuries to Leslie Morris resulting from the injuries to her daughter.

11. GSK obtained FDA approval to manufacture and sell Zofran in 1991 to treat chemotherapy and/or radiation therapy induced nausea and/or vomiting.

12. At least as early as 1998, GSK undertook an off-label marketing campaign to market Zofran to obstetric and gynecology (ob/gyn) health care practitioners as a safe and effective treatment of a very common side effect of normal pregnancy—pregnancy-related nausea and vomiting—otherwise known as morning sickness.

13. Since at least the 1980s, GSK has known from the results of the Zofran preclinical studies that Zofran ingested during pregnancy in mammals crosses the placental barrier to expose the developing fetus to the drug.

14. Prior to GSK's campaign to market Zofran off-label as a safe and effective treatment for morning sickness, GSK knew that animal fetuses exposed to Zofran *in utero* had experienced fetal death, delayed ossification, and other signs of fetal toxicity.

15. As early as 1992, prior to GSK's campaign to market Zofran off-label as a safe and effective treatment for morning sickness, GSK had received numerous adverse event reports of birth defects, including congenital heart defects and other major malformations, associated with Zofran exposure *in utero*.

16. Presently, GSK has received more than 200 reports of birth defects in children who were exposed to Zofran *in utero*.

17. Prior to and during GSK's campaign to market Zofran off-label as a safe and effective treatment for morning sickness, GSK knew or should have known that observational data existed which supported an increased risk of cardiac malformations and other major malformations in children exposed to Zofran *in utero*.

18. GSK has never tested whether it is safe to expose a pregnant woman or a fetus to Zofran.

19. GSK has never sought approval to market Zofran as a safe and effective treatment of morning sickness.

20. GSK's Zofran product label fails to warn of and conceals any risk of birth defects in children who are exposed to Zofran *in utero*.

21. As the innovator of Zofran, at all times relevant GSK was responsible for revising the Zofran label to include a warning as soon as there was reasonable evidence of an association of a serious hazard with using Zofran, even in the absence of a proven causal relationship. 21 C.F.R. § 201.57(e).

22. As the innovator of Zofran, GSK was responsible for ensuring that the Zofran product label provided adequate labeling for known or knowable unapproved, off-label

indications, including any use to treat morning sickness in pregnant women. *See* 21 C.F.R. § 201.57(e).

23. At least as of 1998, GSK knew that its off-label promotion of Zofran to treat morning sickness had resulted in a substantial increase in Zofran sales revenue.

24. GSK's promotion of Zofran for the off-label indication of morning sickness without appropriate testing, without fair and balanced labeling and/or warnings, and without any type of regulatory approval rendered Zofran's product label inadequate, defective, and deceptive.

25. GSK's representations and misrepresentations about Zofran, including GSK's promotion of Zofran as a safe and effective treatment for morning sickness and GSK's failure to include any information in the Zofran label regarding the risk of birth defects in children exposed to Zofran *in utero,* were made with the intent to defraud and deceive Plaintiff Morris's physician, Plaintiff Morris, and the public and medical community in general into using Zofran to treat morning sickness.

26. On March 9, 1999, the FDA's Division of Drug Marketing, Advertising, and Communications ("DDMAC") notified GSK that the FDA had become aware of GSK's promotional materials for Zofran that violated the Federal Food, Drug, and Cosmetic Act and its implementing regulations. The FDA reviewed the promotional material and determined that "it promotes Zofran in a manner that is false or misleading because it lacks fair balance." (FDA Letter to Michele Hardy, Director, Advertising and Labeling Policy, GSK, March 9, 1999.)

27. GSK's promotional labeling under consideration included promotional statements relating to the effectiveness of Zofran, such as "Zofran Can," "24-hour Control," and other promotional messages. But the promotional labeling failed to present any information regarding the risks associated with using Zofran during pregnancy. *Id.*

28. In its March 9, 1999, letter, the FDA directed GSK to "immediately cease distribution of this and other similar promotional materials for Zofran that contain the same or similar claims without balancing risk information." *Id.*

29. GSK blatantly disregarded this mandate by FDA. For example, in 2002, GSK's marketing materials to Ob/Gyn practitioners emphasized Zofran's "Pregnancy Category B" designation on the very first page of the marketing material, creating a false impression that the safety of using Zofran during pregnancy had been established. GSK's materials failed to disclose any of its internal information concerning the risks of birth defects associated with Zofran treatment during pregnancy.

30. GSK's promotion of Zofran for use during pregnancy eventually led to a federal governmental investigation. On July 2, 2012, the Department of Justice announced that GSK "agreed to plead guilty and pay $3 Billion to resolve its criminal and civil liability arising from the company's unlawful promotion of certain prescription drugs," which included Zofran among numerous others. *See* DOJ Press Release, *GlaxoSmithKline to Plead Guilty and Pay $3 billion to Resolve Fraud Allegations and Failure to Report Safety Data* (July 2, 2012).

31. Part of GSK's civil liability to the government included payments arising from the facts that (a) GSK promoted Zofran and disseminated false representations about the safety and efficacy of Zofran concerning pregnancy-related nausea; and (b) GSK paid and offered to pay illegal remuneration to health care professional to induce them to promote and prescribe Zofran.

32. GSK's conduct with respect to Zofran was fraudulent, negligent, and in violation of the Alabama Deceptive Trade Practice Act, Ala. Code § 8-19-5.

33. Z.M. was exposed to Zofran that was manufactured by certain manufacturers of the generic form of that product. At all times relevant, the label for the generic form of the Zofran product ingested by Z.M. was identical to GSK's Zofran label.

34. Had GSK fulfilled its legal obligation to update the name brand Zofran product label with fair and balanced product safety information, including safety information pertinent to the use of Zofran for morning sickness and information regarding the risk of birth defects in children exposed to Zofran *in utero*, the manufacturers of the Zofran ingested by Z.M. would have been legally obligated to update their generic Zofran product labels. *See Wyeth v. Weeks*, 159 So. 3d 649, 660-61 (Ala. 2014) (citing *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011)).

35. Despite Z.M.'s exposure to Zofran manufactured by the manufacturers of the Zofran product ingested by Z.M., GSK, as the innovator responsible for the information in the Zofran label, is liable for injuries resulting from false, misleading, and otherwise deceptive information in the Zofran product label. *See Wyeth v. Weeks*, 159 So. 3d 649, 660-61 (Ala. 2014) (citing *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011)).

36. As a direct and proximate result of GSK's tortious and deceptive conduct as described herein, Plaintiff Morris was prescribed and she did ingest Zofran to treat her pregnancy-related nausea, which led to Z.M. being exposed to Zofran in utero and Z.M. being born in 2007 with significant congenital birth defects.

37. Had Plaintiff Morris known the truth about Zofran's unreasonable risk of harm, she would have never taken Zofran, and Z.M. would not have been injured as described herein.

38. As a direct and proximate result of GSK's deceptive and tortious conduct as described herein, Z.M. suffers from physical injuries, some or all of which are permanent and/or may be fatal, and Z.M. may suffer in the future from other diseases or conditions which have not

yet been diagnosed. Further, Z.M. has sustained in the past, and will sustain in the future, pain and suffering, mental anguish, embarrassment and humiliation, psychological injury, disability, disfigurement caused by the surgeries and procedures she has already undergone, and the surgeries and procedures that she will need to undergo in the future, and the loss of enjoyment of the pleasures of life without the presence of congenital birth defects, and/or other related conditions, as well as past and future general and special damages, including past and future medical care and treatment, lost wages and lost earning capacity.

39. As a direct and proximate result of GSK's deceptive and tortious conduct as described herein, Plaintiff Leslie Morris has suffered severe emotional distress and suffering as a result of the injuries to her child. Every day, Plaintiff Morris lives in fear of what could happen to Z.M. and the effect her condition has and will continue to have on her daily activities.

40. Plaintiffs' serious and permanent injuries were the foreseeable and proximate result of GSK's acts and/or omissions, including, but not limited to, dissemination of inaccurate, misleading, materially incomplete, false, and otherwise inadequate information regarding the safety profile of Zofran to the medical community, including Leslie Morris's physicians, and consumers, including Leslie Morris.

COUNT I
FRAUDULENT MISREPRESENTATION

41. Plaintiffs incorporate by reference all of the above paragraphs as if set forth in full herein.

42. GSK falsely, fraudulently, intentionally, and/or negligently misrepresented to the public, and to Plaintiff Morris, both directly and by and through her prescribing physicians, the safety and effectiveness of Zofran when used by expectant mothers and/or fraudulently,

intentionally, and/or negligently concealed, suppressed, and/or omitted material, adverse information regarding the safety and effectiveness of Zofran when used by expectant mothers.

43. GSK falsely and fraudulently represented to the expectant mothers and the medical and health care community, including Plaintiff and her physicians, that Zofran was safe and effective for treating pregnancy-related nausea and that there was no data to suggest that Zofran was toxic or teratogenic in fetal organogenesis.

44. The representations made by GSK were material, false, and misleading.

45. When GSK made these representations, it knew they were false.

46. GSK made these representations with the intent of defrauding and deceiving the public in general, and the medical and health care community in particular, and with the intent to induce the public in general, and the medical and health care community in particular, including Plaintiff Leslie Morris and her prescribing physician, to recommend, prescribe, dispense, and/or purchase Zofran to treat pregnancy-related nausea, all of which evinced a callous, reckless, willful, depraved indifference to the health, safety, and welfare of Plaintiffs herein.

47. At the time the aforesaid representations were made by GSK, and at the time Plaintiff Morris used Zofran, she was unaware of the falsity of said representations and reasonably believed them to be true.

48. In reliance upon said representations, Plaintiff's prescribing physician was induced to prescribe Zofran to her, and Plaintiff was induced to and did use Zofran to treat pregnancy-related nausea.

49. GSK knew that Zofran had not been sufficiently tested for pregnancy-related nausea and that it lacked adequate warnings.

50. GSK knew or should have known that Zofran exposure *in utero* increases the risks of developing birth defects.

51. As a result of the foregoing acts and omissions, Z.M. was caused to suffer birth defects that are permanent and lasting in nature, as well as physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications.

52. Plaintiff Morris also has sustained severe emotional distress and suffering as a result of GSK's wrongful conduct and the injuries to her child.

53. As a result of the foregoing acts and omissions, Z.M. requires and will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff Morris is informed and believes and further alleges that Z.M. will in the future be required to obtain further medical and/or hospital care, attention, and services.

54. By reason of the foregoing, Plaintiffs have been damaged by GSK's tortious and deceptive conduct. GSK's willful, wanton and deliberate disregard for the rights and safety of consumers of Zofran, including Plaintiff Morris and Z.M., justifies an award of punitive damages.

COUNT II
FRAUDULENT CONCEALMENT

55. Plaintiffs incorporate by reference all of the above paragraphs as if set forth in full herein.

56. In representations to the FDA, health care providers, including Plaintiff's health care providers, and expectant mothers, including Plaintiff, GSK fraudulently concealed and intentionally omitted the following material facts:

(a) GSK was illegally paying and offering to pay doctors remuneration to promote and prescribe Zofran;

(b) Zofran had not (and has not) been tested or studied in pregnant women at all;

(c) *in utero* Zofran exposure increases the risk of birth defects;

(d) the risks of birth defects associated with the consumption of Zofran by pregnant women were not adequately tested prior to GSK's marketing of Zofran;

(e) the safety and efficacy of Zofran for treating pregnancy-related nausea has not been established;

(f) Zofran is not safe and effective for treating pregnancy-related nausea; and

(g) GSK's internal data and information associated Zofran usage during pregnancy with birth defects.

57. GSK's concealment and omissions of material facts concerning, among other things, the safety and efficacy of Zofran for pregnancy-related nausea was made purposefully, willfully, wantonly, and/or recklessly, to mislead physicians, hospitals and health care providers, and expectant mothers including Plaintiff Leslie Morris into reliance, continued use of Zofran, and to cause them to promote, purchase, prescribe, and/or dispense Zofran.

58. GSK knew that physicians, hospitals, health care providers and expectant mothers, such as Plaintiff Morris, had no way to determine the truth behind GSK's concealment and material omissions of facts surrounding Zofran, as set forth herein.

59. Plaintiff Morris and her prescribing physicians reasonably relied on GSK's promotional statements concerning Zofran's asserted safety and efficacy in pregnant women, from which GSK negligently, fraudulently, and/or purposefully omitted material facts.

60. As a result of the foregoing acts and omissions, Z.M. was caused to suffer serious birth defects, as well as other severe and personal injuries which are permanent and lasting in

nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications.

61. Plaintiff Leslie Morris also has sustained severe emotional distress and suffering as a result GSK's wrongful conduct and the injuries to her child.

62. As a result of the foregoing acts and omissions, Plaintiff Z.M. requires and will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Z.M. will in the future be required to obtain further medical and/or hospital care, attention, and services.

63. By reason of the foregoing, Plaintiffs have been damaged by GSK's tortious and deceptive conduct. GSK's willful, wanton, and deliberate disregard for the rights and safety of consumers of Zofran and those babies exposed to Zofran in utero, including Z.M., justifies an award of punitive damages.

COUNT III
NEGLIGENT MISREPRESENTATION

64. Plaintiffs incorporate by reference all of the above paragraphs as if set forth in full herein.

65. GSK falsely and negligently represented to the medical community and expectant mothers, including Plaintiff, and her prescribing physicians, that Zofran was safe and effective for treating pregnancy-related nausea.

66. The representations made by GSK were, in fact, false and misleading.

67. As a result of the foregoing acts and omissions, Plaintiff Z.M. has suffered serious birth defects, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring, and/or medications.

68. As a result of the foregoing acts and omissions, Plaintiff Z.M. requires and will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff Morris is informed and believes and further alleges that Z.M. will in the future be required to obtain further medical and/or hospital care, attention, and services.

69. Plaintiff Morris also has sustained severe emotional distress and suffering as a result of GSK's wrongful conduct and the injuries to her child.

70. By reason of the foregoing, Plaintiffs have been damaged by GSK's tortious and deceptive conduct. GSK's willful, wanton and deliberate disregard for the rights and safety of consumers of Zofran, and those babies exposed to Zofran *in utero*, including Z.M., justifies an award of punitive damages.

COUNT IV
VIOLATION OF ALABAMA DECEPTIVE TRADE PRACTICES ACT

71. Plaintiffs incorporate by reference all of the above paragraphs as if set forth in full herein.

72. GSK had a statutory duty to refrain from making false or fraudulent representations and/or from engaging in deceptive acts or practices in the sale and promotion of Zofran pursuant to Ala. Code § 8-19-5.

73. GSK engaged in unfair, deceptive, false and/or fraudulent acts and/or practices in violation of Alabama Consumer Protection Laws through its false and misleading promotion of Zofran designed to induce Plaintiff's prescribing physician to prescribe and Plaintiff Morris to ingest Zofran.

74. GSK's conduct as described herein constituted unfair and deceptive acts and practices, including, but not limited to:

a. Publishing instructions and product material containing inaccurate and incomplete factual information;

b. Misrepresenting the nature, quality, and characteristics about Zofran; and

c. Engaging in fraudulent or deceptive conduct that creates a likelihood of confusion or misunderstanding.

75. GSK marketed Zofran as an effective and safe treatment for morning sickness, despite GSK failing to prove that Zofran was safe and effective for the treatment of morning sickness.

76. GSK misrepresented the alleged benefits of Zofran, including the unapproved benefit of the treatment of morning sickness, failed to disclose material information concerning the known side effects of Zofran, including any adverse risk information associated with the use of Zofran in pregnancy, and otherwise engaged in fraudulent and deceptive conduct which induced Plaintiff Morris's physician to prescribe and Plaintiff Morris to ingest Zofran for treatment of her morning sickness.

77. GSK uniformly communicated the purported benefits of Zofran, even if those purported benefits had not been proven or approved, while failing to disclose the serious and dangerous side-effects related to the use of Zofran, its safety, its efficacy, and its usefulness. GSK made these representations to physicians, the medical community at large, and to patients and consumers such as Plaintiff Morris in Zofran marketing and advertising campaigns.

78. GSK's conduct in connection with Zofran was impermissible and illegal in that it created a likelihood of confusion and misunderstanding, because GSK misleadingly, falsely, and/or deceptively misrepresented and omitted numerous material facts regarding, among other things, the utility, benefits, costs, safety, efficacy and advantages of Zofran.

79. GSK's conduct as described above was a material cause of Plaintiff Morris's decision to ingest Zofran.

80. As a direct, foreseeable, and proximate cause of GSK's conduct in violation of Ala. Code. § 8-19-5, Plaintiff Morris and Z.M. suffered damages. GSK's conduct was wanton, egregious, and reckless, warranting an award of treble damages.

CONCLUSION AND PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demand judgment against GSK as follows:

A. For general damages in a sum in excess of the jurisdictional minimum of this Court;

B. For medical, incidental and hospital expenses according to proof;

C. For pre-judgment and post-judgment interest as provided by law;

D. For full refund of all purchase costs of Zofran;

E. For consequential damages in excess of the jurisdictional minimum of this Court;

F. For compensatory damages in excess of the jurisdictional minimum of this Court;

G. For punitive damages in an amount in excess of any jurisdictional minimum of this Court in an amount sufficient to deter similar conduct in the future and punish the Defendant for the conduct described herein;

H. For treble damages pursuant to the Alabama Deceptive Trade Practices Act;

I. For attorneys' fees, expenses and costs of this action; and

J. For such further and other relief as this Court deems necessary, just and proper.

JURY DEMAND

Plaintiffs request a jury trial on all issues.

Dated: October 30, 2015

Respectfully Submitted,

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